UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,739	02/14/2001	Surya K. Goli	PF-0162-3 DIV	3353

27904 7590 01/08/2004

INCYTE CORPORATION
3160 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	It	GOLI ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ they raise the issue of new matter (see Note below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *2-4 and 8*.

   Claim(s) withdrawn from consideration: _____.
8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 5. does NOT place the application in condition for allowance because: applicants have failed to submit a terminal disclaimer the rejection of claim 8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-4 of U.S. Patent No.5,817,497 is maintained. Applicants request that the requirement for submission of a terminal disclaimer be held in abeyance is noted, however the rejection will be maintained until the terminal disclaimer is received. It is noted that non-compliance with the requirements of the rejection will cause the rejection to be maintained

The written description is not commensurate in scope with the claims drawn to a naturally-occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 over the entire length of SEQ ID NO:1 and a naturally-occurring polynucleotide sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2, therefore the rejection of claims 2-4 and 8 under 112 1st paragraph is maintained.
Contrary to applicants assertion, there is no teaching of naturally occurring sequences having at least 90% sequence identity to the sequence of SEQ ID NO:1 and 2 over the entire length of sequences. The specification

fails to describe naturally occurring sequence variations having at least 90% sequence identity to SEQ ID NO:1 and 2 over their entire length. BLAST fails to adequately describe the naturally occurring sequence variations. The rejection is maintained because the specification fails to adequately described naturally-occurring sequences having at least 90% sequence identity to the sequence of SEQ ID NO:1 over the entire length of SEQ ID NO:1 and naturally-occurring polynucleotide sequences having at least 90% sequence identity to the sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2. Applicant claims sequences that are naturally occuring, however applicant has failed to describe these sequences. Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. There is no disclosure of naturally occurring amino acid sequences having at least 90% sequence identity to the sequence of SEQ ID NO:1 over the entire length of SEQ ID NO:1 and naturally occurring polynucleotides sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2. The description fails to teach a naturally occurring polynucleotide having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2 and applicants arguments do not overcome the failure. Applicant has failed to described what sequence will naturally occurring sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. Contrary to applicants arguments, the instant claims fail to define the polynucleotides in terms of chemical structure, as applicants have not described what the naturally occurring sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2 are. Neither have applicants described the process by which they can determine what the naturally occurring sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 nor 2 over the entire length of SEQ ID NO:1 or 2 will be.
Applicants argue that the instant claims do not describe a genus that could be characterized as highly diverse and that the variation is low. However the instant claims are drawn to naturally occurring sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2, yet there is no written description drawn to the variation of the naturally occurring sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. Applicants have failed to describe how to predict what the naturally occurring sequences having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. Furthermore any variant or mutant that has similar sequence identity yet has a different function is also encompassed by the claims. Applicants have not taught examples of such polynucleotides and ribonucleotides. Thus, the structure of sequences or complementary polynucleotides that encode a polynucleotide having sufficient glutathione S-transferase activity have not defined and broaden the scope of the invention to encompass polynucleotides not described by the instant specification.

Despite applicants assertions, there are no assays for determining naturally occurring sequences which support allowing one of skill in the art to screen for such naturally occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. These naturally occurring variant sequences are not described. The specification does not provide written description support for any naturally occurring sequences having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. The specification fails to describe how to predict such natural occurrences.The skilled artisan cannot envision the detailed structure of the encompassed naturally occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. It is noted that the naturally occurring variations can vary at critical residues, yet the claims fail to define or take into account what the 10% naturally occurring variables will be. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). There is no written description support that the inventors control what naturally occurs. There is no written description support that the inventors invented naturally occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. The specification only discloses SEQ ID NO: 1 or 2, there is no disclosure of naturally occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2 or complementary sequences comprised within the family of enzymes. Thus, the structure of these naturally occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2 or polynucleotides is not defined. Moreover, a skilled artisan cannot envision the detailed structure of complementary sequences. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for determining sequence identity or the advances in technology. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression.The nucleic acid itself is required.
It is noted that aplicants have requested rejoiner, however the claims drawn towards methods for detecting a polynucleotide using hybridization, amplification, methods of screening for effectivness and methods for assessing toxicity would require further search and consideration, thus rejoinder is not appropriate.

Thus the claims fail to recite the precise definition of the naturally occurring variants having at least 90% sequence identity to the sequence of SEQ ID NO:1 or 2 over the entire length of SEQ ID NO:1 or 2. Therefore, the full breadth of the claims fails to meet the

written description provision of 35 USC 112, first paragraph and the rejection is maintained.